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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/834,442 | 04/13/2001 | John S. Whitaker | 29342/37225 | 2950 |

7590

06/04/2003

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/04/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,442

Applicant(s)

WHITAKER ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11,13,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11,13,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2003 has been entered.

Applicant's terminal disclaimer submitted January 14, 2003, is persuasive to remove the double patenting rejection in the final office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan et al. (WO 96/32003).

Daugan et al. (WO 96/32003) teaches a pharmaceutical composition comprising a PDE-5 inhibitor compound of formula I, see abstract. Daugan et al. (WO 96/32003) teaches that its pharmaceutical composition can be used to treat erectile dysfunction, see particularly page 7, line 34 and page 8 line 1. Daugan et al. (WO 96/32003) shows that the compounds of formula I exhibit an IC₅₀ value of less than 10 nM, see particularly Table 1. Daugan et al. (WO 96/32003) also teaches that the preferred route of administration is oral, and that the dosage range is from

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0.5-800 mg, individual tablets contain from 0.2-400 mg of the active compound in a suitable pharmaceutically acceptable carrier, for administration in single or multiple doses, once or several times per day (which may constitute chronic administration), see particularly page 9, lines 5-11. Daugan et al. (WO 96/32003) also teaches that its pharmaceutical composition can be used in treating cardiovascular disorders, e.g. conditions of reduced blood vessel patency, peripheral vascular disease, see particularly page 7, lines 21 to page 8, line 2.

Daugan et al. (WO 96/32003) does not teach the inclusion of a package insert or a container.

It would have been obvious to one of ordinary skill at the time the invention was made to include the PDE-5 active herein in a container and to include the package insert herein for the therapeutic composition.

One of ordinary skill in the art would have been motivated to include the therapeutic agent comprising PDE5 in a container since the packaging of pharmaceutical compositions is widely practiced in the art and is therefore within the skill of the artisan. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806).

Claims 1-2, 5-11,13, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan WO 97/03675 (submitted by the applicant in the parent application 09/558911, August 29, 2001), and *Remington: The Science and Practice of Pharmacy* (of record in the previous office action).

Daugan teaches compounds of formula I (which reads on formula I of the instant application) in general and the two particular compounds recited in claim 10 herein in an article useful in treating erectile dysfunction in a dose of 0.5-800 mg/day, see abstract, claim 4 and page 5 in particular. Daugan also teaches that its composition can be administered in single or multiple doses, once or several times a day, see page 5.

WO 97/03675 does not teach the inclusion of a package insert, nor does it disclose a container.

It would have been obvious to one of ordinary skill at the time the invention was made to include the PDE-5 actives herein in a container and to include the package insert herein for the therapeutic composition.

One of ordinary skill in the art would have been motivated to include the therapeutic agent comprising PDE5 herein in a container since the packaging of pharmaceutical compositions in articles is widely practiced in the art and is therefore within the skill of the artisan. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806).

Response to Arguments

Applicant's arguments with respect to the '433 patent and viagra prescribing information have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the chronic dosage regimen herein have been considered, but are not persuasive. Applicant argues that the claimed invention differs from the cited prior art in that the instant invention requires a chronic dosage regimen. Note that the cited references broadly teach that their compositions can be administered in single or multiple doses, once or several times a day. The teaching of the prior art (specifically '675 patent) is not an on-demand regimen, contrary to the applicant's assertion.

Applicant then argues that the printed material on the package insert should be given patentable weight. Applicant argues that the instant case is analogous to the *In re Miller* 164 USPQ 46 (CCPA1969) and *In re Gulack* 217 USPQ 401 (CAFC) 1983. Note that the *Miller* Court relies on the fact that there is a functional relationship between a measuring cup and the indicia (printed material) on the cup. A cup is not a measuring cup without the indicia since one cannot employ the cup (without indicia) to take accurate measurements. The instant case is distinguishable from *Miller* since a patient can take a medication even without having the instructions at hand. The ultimate function of the instant article of manufacture relies not on the instructions, but on the active pharmaceutical ingredient, i.e., the PDE5 inhibitor, contained therein.

The Court in *In re Gulack* also states that "where the printed material is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Here, the set of instructions is not functionally related to the article of manufacture because the article of manufacture can function as an active and effective drug even in the absence of the set of instructions (i.e., package insert). Therefore following the reasoning

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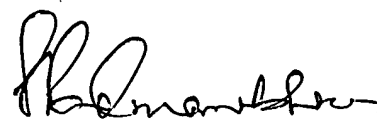
in *Miller* and *Gulack*, we can conclude that the "printed material", i.e., the package insert, does not patentably distinguish the instant claims over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
April 4, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

6/1/03